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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,825 07/17/98 GRONHOJ LARSEN

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HM12/0722

EXAMINER

HAMUD, F

ART UNIT

PAPER NUMBER

1646

10

DATE MAILED:

07/22/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File copy

# Office Action Summary

Application No.  
09/101,825

Applicant(s)  
Larsen et al

Examiner  
Fozia Hamud

Group Art Unit  
1646



☒ Responsive to communication(s) filed on Mar 18, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 18-48 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 18-48 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

X Notice with to comply with sequence rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. This application is a 371 of PCT/DK97/00021. For application filed under 371, PCT rules for lack of unity apply.

2. Claims 1-17 have been canceled and new claims 18-48 have been added in Paper No.8 filed on 1/29/99. Claims 18-48 are pending and under consideration by the Examiner.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1, and restriction to one of the groups is required.

I. Claims 18-46 and 48, drawn to a polypeptide comprising 100 amino acids, a pharmaceutical composition comprising said polypeptide and a method of treating or preventing a disease.

II. Claims 47 drawn a process for synthesizing a polypeptide.

The inventions listed as Groups I-II do not meet the requirements for Unity of Inventions for the following reasons:

Groups I-II are drawn to separate, distinct methods and are distinguished from each other because the special technical features which define them by the steps in the method, starting material and goals are different and these special technical features are not shared by each invention. Since these technical features are not shared by each method and since the common features do not

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establish an advance over the prior art because the methods can be practiced with other products, the inventions of Groups I-II do not form a single inventive concept within the meaning of Rule 13.1.

Claims 42-46 are directed to methods of treatment for numerous species of diseases using the claimed polypeptide product.

The species recited in claims 42-46 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: These species of diseases are different with different symptoms and causes and can be treated with different products.

Applicant is required, in reply to this action, to elect a method of treatment for a single disease to which the claims shall be restricted. The reply must also identify the claims readable on the elected disease, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

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Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

F<sup>n</sup>  
Fozia Hamud  
Patent Examiner  
Art Unit 1646  
July 20, 1999

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER